



**Map key:**

- ↑ with dotted line - Represents legal relationship without physical transfer of legend drugs.
- ↑ with full line - Represents physical transfer of legend drugs

**Red Boundary - Business does require licensure in Indiana**

**Green Boundary - Business does not require licensure in Indiana**

 Contractual relationship only (no physical possession of legend drug)

 NDA/patent holder

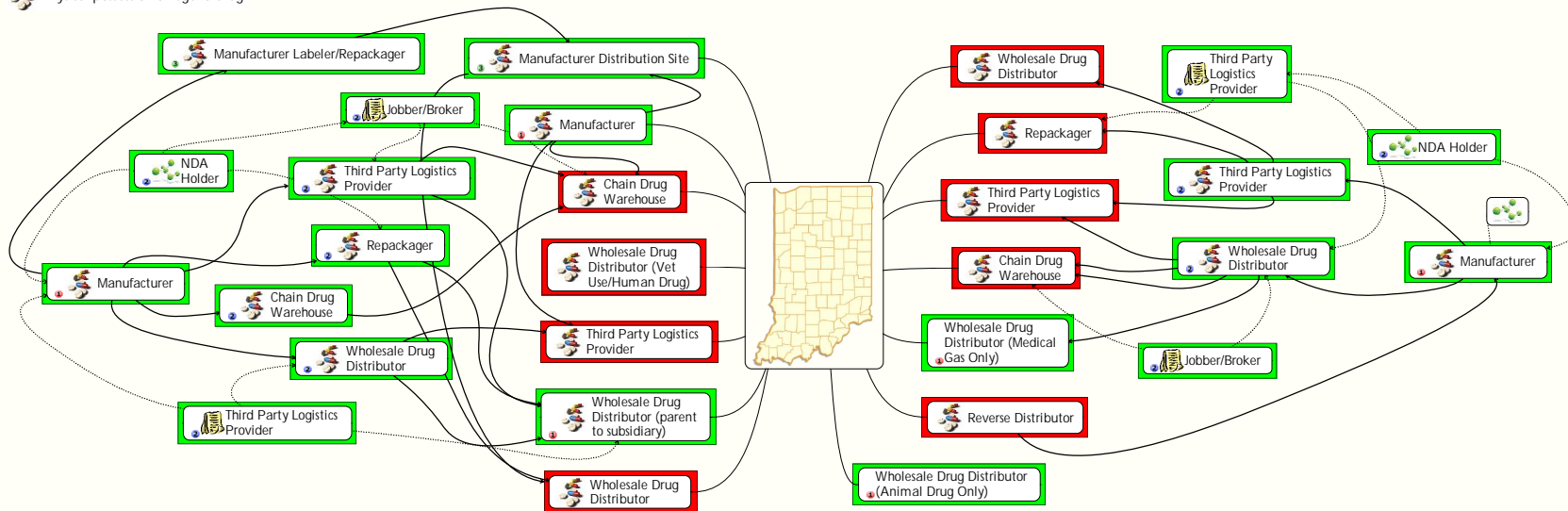
 Physical possession of legend drug



NABP does not provide legal interpretation or guidance relative to licensing nor do we make decisions relative to licensing in any state, we believe this Indiana map is consistent with:

1. NABP's understanding of Indiana laws and regulations;
2. Businesses that have previously and are presently pursuing VAWD accreditation; and
3. NABP's Model Rules for Licensure for Wholesale Distributors, which although not legally binding are the foundation on which the VAWD program is built.

## Indiana Wholesale Drug Distribution Licensure Requirements Map



### Reasons why entity is not required to be licensed in Indiana:

**GENERAL STATUTORY EXEMPTIONS** - Indiana law explicitly excepts this business or business practice from licensure, i.e. manufacturer, animal drug only, OTC only, common carrier (e.g. UPS), medical gas supply only, or parent to subsidiary transactions.

**"IN INDIANA" REQUIREMENT** - The business is not physically distributing legend drugs within or into Indiana; IC 25-26-14-1 states, in part, as follows: This chapter applies to any individual, partnership, limited liability company, corporation, or business firm: located in or outside Indiana; and engaging in the wholesale distribution of legend drug in Indiana. That is, the business either (a) does not physically possess the drug in the distribution process or (b) does not ship legend drugs within or directly into Indiana.

**MANUFACTURER EXEMPTION DEFINED** - A company that is a FDA approved NDA, ANDA or BLA holder may distribute legend drugs it manufactures within or into Indiana from all of its FDA approved sites without a WDD license. This includes FDA approved repackagers, labelers, or distribution locations. **This exemption does not apply to a FDA approved entity that distributes, repackages, or labels legend drugs that it does not manufacture.** Note also that FDA approval for medical devices or OTC drugs does not exempt a company from licensure if it is also distributing legend drugs.

### Additional Information :

- \* The licensure requirements referenced herein do not serve in any capacity to inform , advise or direct licensees on Indiana pedigree requirements.
- \* There is no VAWD exemption for businesses requiring licensure, i.e. if a business is required to be licensed as a Wholesale Drug Distributor in Indiana, the business must be VAWD accredited.